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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,767	03/17/2000	Wolfgang Kreiss	LeA 33 072	3608

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/527,767	KREISS ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 27 is acknowledged and has been entered.

2. Claims 27-43 are currently pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-29, 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Still et al. [US 5,565,324].

With respect to claim 27, Still et al. teach a system where cells (biological sensor material) may be embedded substantially homogeneously in a gel which may be polyacrylamide, agarose, gelatin, etc. (diffusion controlling matrix) (column 31, line 62 – column 32, line 6). One could further place a grid over the gel defining areas of one or no particle (column 32, lines 6-15). Still et al. further discloses assays where one could release the product, incubate for a sufficient time, followed by spreading a vital dye over the gel, so that cells which absorbed the dye or did not absorb the dye could then be distinguished (means for detecting spatial distribution) (column 32, lines 10-15). By employing recombinant techniques, the cells can be designed such that binding to a surface membrane protein will result in an observable signal, such as a fluorescent product (bioluminescent cells) (column 30, lines 35-45).

5. With respect to claim 28, Still et al. further teach beads and particles(carrier) (column 4, line 66 – column 67, line 10) having an attached product with a desired property (column 31, lines 25-30) and spreading the particles over the gel (column 32, lines 1-10).

6. With respect to claim 29, cells may be embedded in agarose (column 31, lines 65-67).

7. With respect to claim 31, Still et al. further teach enzymes which may provide a detectable signal (column 32, lines 18-25) as well as antibodies located on the particles (column 30, lines 45-51).

8. With respect to claims 32, 33, Still et al. teach that different cells may be associated with different particles, such that particles containing active compounds may be identified (column 30, lines 43-50).

9. With respect to claims 34-35, Still et al. teach the incubation of the beads in a buffer (column 15, liens 63-67).

10. With respect to claim 36, Still et al. further teach chemiluminescers (column 27, liens 25-27).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still et al. [US 5,565,324] in view of Simpson et al. [US 6,117,643].

With respect to claim 37, Still et al. teach a system where cells (biological sensor material) may be embedded substantially homogeneously in a gel which may be polyacrylamide, agarose, gelatin, etc. (diffusion controlling matrix) (column 31, line 62 – column 32, line 6). One could further place a grid over the gel defining areas of one or no particle (column 32, lines 6-15). Still et al. further discloses assays where one could release the product, incubate for a sufficient time, followed by spreading a vital dye over the gel, so that cells which absorbed the dye or did not absorb the dye could then be distinguished (means for detecting spatial distribution) (column 32, lines 10-15). By employing recombinant techniques, the cells can be designed such that binding to a surface membrane protein will result in an observable signal, such as a fluorescent product (bioluminescent cells) (column 30, lines 35-45). Still et al., however, do not teach a plurality of sheets of diffusion controlling matrices containing different constituents.

Simpson et al., however, teach that layers of encapsulation may be produced, in order to provide the cells with a greater degree of protection than a single layer alone (column 69, lines 35-43). Simpson et al further teach multiple biofilms (diffusion controlling matrices) comprising different bioreporters, such as cells (column 2, lines 48-53), enclosed in a polymer matrix (column 7, lines 65-67), which may be placed in an array, allowing for several different bioreporters to be tested simultaneously (column 4, lines 45-50). One would have been motivated to do this, in order to speed up the process of assaying different compounds.

Therefore, it would have been obvious in to have a plurality of sheets of diffusion controlling matrices such as biofilms in the invention of Still et al., as suggested by Simpson et

al., in order to speed up the process of assaying different compounds by allowing for several different bioreporters to be tested simultaneously.

13. With respect to claims 38-39, Simpson et al. teach that cells may be added to molten agar or agarose of 1% to 5% (column 68, lines 48-50). Therefore, in 50 mL of the agar or agarose, there would be 2 to 10 mL of cells. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

14. With respect to claim 40, Still et al. do not teach that the matrix has an optical density of 0.6 to 1.4 at 660 nm. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, one of ordinary skill in the art would have been motivated to produce a matrix with an optical density of 0.6 to 1.4 at 660 nm through normal optimization techniques known in the art.

15. With respect to claims 41-43, Simpson et al. teach that the sheets can be 0.1-2 mm (column 68, lines 39-41). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Still et al. [US 5,565,324] in view of Ribi [US 5,156,810].

With respect to claim 30, Still et al. teach a system where cells (biological sensor material) may be embedded substantially homogeneously in a gel which may be polyacrylamide, agarose, gelatin, etc. (diffusion controlling matrix) (column 31, line 62 – column 32, line 6). One

could further place a grid over the gel defining areas of one or no particle (column 32, lines 6-15). Still et al. further discloses assays where one could release the product, incubate for a sufficient time, followed by spreading a vital dye over the gel, so that cells which absorbed the dye or did not absorb the dye could then be distinguished (means for detecting spatial distribution) (column 32, lines 10-15). By employing recombinant techniques, the cells can be designed such that binding to a surface membrane protein will result in an observable signal, such as a fluorescent product (bioluminescent cells) (column 30, lines 35-45). Still et al., however, the use of polyacrylate.

Ribi, however, teaches that polyacrylate is inert and has good electrical insulating properties, is smooth at the molecular level, and has good adhering properties (column 3, lines 27-35).

Therefore it would have been obvious to use polyacrylate as the polymer in the biosensors of Still et als, as suggested by Ribi, since polyacrylate is inert and has good electrical insulating properties, is smooth at the molecular level, and has good adhering properties, and therefore would not interfere with the optical detection of the presence of substances.

Response to Arguments

17. Applicant's arguments with respect to claims27-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

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